SPECIALTY
ULTRAVISION INC.

FEB 1 2 2001

510(k) Summary

K003526

Submitter Information:

Specialty UltraVision, Inc.
307 Orchard City Drive, Suite 100
Campbell, CA 95008

Contact Person: Garold L. Edwards, O.D., F.A.A.O.
Vice President, Technical Affairs

Telephone: (408) 341-0700
Fax: (408) 341-0717

Date Prepared: October 31, 2000

Device Name:

Common Name:	Soft (Hydrophilic) Contact Lens
Trade/Proprietary Names:	Specialty 55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
	Specialty 55 UV Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
	Specialty 55 UV Toric (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
Classification Name:	Soft (Hydrophilic) Contact Lens
Device Classification:	Class II (21 CFR 886.5925)

Predicate Devices:

The Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens, the Specialty 55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens and the IGEL 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens were selected as the predicate devices.

The Specialty 55, Specialty 55 UV and IGEL 56 UV devices are manufactured in the same facility, under the same quality system, using the same moulding, tinting, packaging and sterilization processes. The Specialty 55 UV lenses contain the same UV blocking agent as the IGEL 56 UV lenses, and the manufacturing process for adding the UV blocking agent is the same.

Description of Devices:

The Specialty 55 UV, the Specialty 55 UV Multifocal, and the Specialty 55 UV Toric Daily Wear Contact Lenses (methafilcon A) are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera. The Specialty 55 UV Contact Lens is available in a single vision lens design, the Specialty 55 UV Multifocal Contact Lens is available in an aspherical lens design, and the Specialty 55 UV Toric Contact Lens is available in a back surface toric design. The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). A UV absorbing compound has been incorporated into the lens polymer. All lenses are tinted using the color additive Reactive Blue #19.

Comparison to Predicate Device

PARAMETER ***Submission number***	***Specialty 55 UV, Specialty 55 UV Multifocal, and Specialty 55 UV Toric Soft (Hydrophilic) Contact Lenses for Daily Wear***	***Specialty 55 Multifocal and Specialty 55 Soft (Hydrophilic) Contact Lenses for Daily Wear*** ***K984090***	***IGEL 56 UV Soft (Hydrophilic) Contact Lens for Daily Wear*** ***K984523***
Material	methafilcon A	methafilcon A	hefilcon C
Material classification	Hydrophilic Lens Group 4	Hydrophilic Lens Group 4	Hydrophilic Lens Group 2
Indication for use	myopia, hyperopia, presbyopia and astigmatism	myopia, hyperopia, and presbyopia	myopia, hyperopia, presbyopia and astigmatism
Water content	55%	55%	56%
Visible light transmittance	90.3%	98.2%	90.3%
UV transmittance	< 10%	N/A	< 10%
Dk (35° C)	18.9×10^{-11}	18.8×10^{-11}	21×10^{-11}
Powers	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters	-12.00 to +6.00 Diopters
Color	blue visibility Reactive Blue #19	blue visibility, Vat Blue #6	blue visibility, D&C Green No. 6
Refractive index	1.42	1.42	1.41
Specific gravity	1.06	1.06	1.16
Method of manufacture	Moulded	Moulded	Moulded

Indications for Use:

The **Specialty 55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The **Specialty 55 UV Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens is** indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The Specialty 55 UV Toric (methafilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not aphakic persons with non diseased eyes that may exhibit refractive and/or corneal astigmatism up to 5.00 diopters.

The lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Specialty 55 UV, the Specialty 55 UV Multifocal, and the Specialty 55 UV Toric (methafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear, and to establish substantial equivalence to the predicate devices.

Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. The Specialty 55 UV lenses were extracted and evaluated for presence of the Reactive Blue #19 tint and the UV blocking compound. Results showed no evidence of unsafe amounts of either compound in the extracts. Physicochemical testing of the Specialty 55 UV lenses demonstrated equivalency to the predicate devices.

Conclusion:

Information submitted in the 510(k) establishes that the Specialty 55 UV, the Specialty 55 UV Multifocal and the Specialty 55 UV Toric Contact Lenses (methafilcon A) have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2001

Garold L. Edwards, O.D, F.A.A.O.
Vice President, Technical Affairs
Specialty Ultravision, Inc.
307 Orchard City Drive
Suite 100
Campbell, CA 95008

Re: K003526
Trade Name: Specialty 55 UV Spherical, Multifocal and Toric (methafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear (Blue visibility tinted with Reactive Blue #19, Cast-molded)
Regulatory Class: II
Product Code: 86 LPL
Dated: November 6, 2000
Received: November 16, 2000

Dear Dr. Edwards:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS STATEMENT

Device Names:

Specialty 55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Specialty 55 UV Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Specialty 55 UV Toric (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

Ph.D.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003526